K060095

Page 1 of 1

FEB 1 0 2006

# 510(K) SUMMARY
# OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the VACLOK™ Syringe.

| | |
|---|---|
| Submitted By: | Wright Medical Technology, Inc. |
| Date: | January 10, 2006 |
| Contact Person: | Wesley L. Reed |
| | Regulatory Affairs Specialist |
| Proprietary Name: | **VACLOK™ Syringe Kit** |
| Common Name: | Piston Syringe |
| Classification Name and Reference: | 21 CFR 880.5860 Piston syringe – Class II |
| Device Product Code and Panel Code: | FMF/General Hospital-80 |

## DEVICE INFORMATION

### A. INTENDED USE

The VACLOK™ Syringe Kit is intended for use as a piston syringe for aspiration of bone marrow, autologous blood, plasma, or other body fluids. The VACLOK™ Syringe Kit can be used to mix bone graft materials with aspirated fluids and deliver the composite graft material to the orthopedic surgical site.

### B. DEVICE DESCRIPTION

The VACLOK™ Syringe is a polycarbonate piston syringe modified to include fins on the plunger and a stopping pin in the barrel. The plunger can be pulled back and turned to lock the fins back with the barrel pin.

### C. SUBSTANTIAL EQUIVALENCE INFORMATION

The design features, material, and indications for use of the VACLOK™ Syringe are substantially equivalent or identical to the previously cleared Bone Graft Syringe (K023088) and the Merit Coronary Control Syringe (K994253). The safety and effectiveness of the VACLOK™ Syringe is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 10 2006

Mr. Wesley L. Reed
Regularly Affairs Specialist
Wright Medical Technology, Inc.
5677 Airline Rd.
Arlington, Tennessee 38002

Re: K060095
Trade/Device Name: Vaclok™ syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: II
Product Code: FMF
Dated: January 10, 2006
Received: January 13, 2006

Dear Mr. Reed:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K060095

Device Name: VACLOK™ Syringe Kit

Indications For Use:

The VACLOK™ Syringe Kit is intended for use as a piston syringe for aspiration of bone marrow, autologous blood, plasma, or other body fluids. The VACLOK™ Syringe Kit can be used to mix bone graft materials with aspirated fluids and deliver the composite graft material to the orthopedic surgical site.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)



Barbara Brennan

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K060095